K113153

NOV 28 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K113153.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5615
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Contact Person:
Tan Chuanbin
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: October 10th, 2011

2. Device Name:

DP-20 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)
DP-30 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)

Classification
Regulatory Class: II
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System are general purpose, portable/mobile (with mobile ultrasound trolley), software controlled, ultrasonic diagnostic systems. Its function is to acquire and display ultrasound data in B-Mode,

M-Mode, or their combined mode B+M Mode. The systems are Track 1 device that employs an array of transducers including linear array and convex array. The frequency range of DP-20 is approximately 2.0 MHz to 10.0 MHz and that of DP-30 is approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular and urology exams.

5. Comparison with Predicate Device:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to the Mindray DP-6900 Digital Ultrasonic Diagnostic Imaging System (K090912), M5 Diagnostic Ultrasound System(K102991) and M7 Diagnostic Ultrasound System(K103677). They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate device.

6. Non-clinical Tests:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, IEC 60601-1-4, ISO 10993-1 and IEC 62304.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC - 6 2011

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
GREAT NECK NY 11021

Re: K113153
Trade/Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: October 10, 2011
Received: October 25, 2011

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of November 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA	65EC10EB	75L53EA
35C50EB	65EL60EA	75LT38EA
65C15EA	75L38EB	35C20EA

35C50EA	65EB10EA	75LT38EA
65C15EA	65EC10ED	10L24EA
65EC10EA	75L38EA	
65EL60EA	75L53EA	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

for

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K113153

Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System

Indications for Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vascular and urology.

Prescription Use__X__ AND/OR Over – The – Counter Use____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: × Transducer: _____

Model: DP-20

510(k) Number(s): K113152

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 1, Note2
Abdominal	N	N					N	Note 1, Note2
Intraoperative (specify)*	N	N					N	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N					N	Note 2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N					N	Note 2
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113152

0030

Diagnostic Ultrasound Indications for Use Form

System —
Transducer M
Model: 35C20EA
510(k) Number(s) k113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal							P	Note 2
Abdominal	P	P						
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic							P	Note 2
Pediatric	P	P						
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intravascular							P	Note 2
Cardiac Adult	P	P						
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Trans-Cardiac							P	Note 2
Peripheral Vascular	P	P						
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer x
Model: 35C50EB
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer x
Model: 65EC10EB
510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N					N	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: Transducer: *
Model: 65EL60EA
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P					P	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other(specify)***	P	P					P	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other can includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

Transducer *

System —
Model: TSL385B
510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N					N	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 2
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer —

Model: 751,53EA

510(k) Number(s) K113153

Clinical Application	Modes of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Cardl.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer —
Model: 7SLT3R2A
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2- Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: Transducer: X
Model: DP-30
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 1, Note2
Abdominal	N	N					N	Note 1, Note2
Intraoperative (specify)*	N	N					N	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N					N	Note 2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: ___ Transducer: x
Model: 35C20EA
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P					P	Note 2
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: — Transducer: x
Model: 35C50RA
510(k) Number(s): k113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 1, Note 2
Abdominal	P	P					P	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 1, Note 2
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Muscalo-skeletal Conventional	P	P					P	Note 1, Note 2
Muscalo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

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*Intraoperative includes abdominal, thoracic, and vascular.

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Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K k113153

Diagnostic Ultrasound Indications for Use Form

System: —
Transducer: x
Model: 65C156A
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**								
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic	P	P					P	Note 2
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Muscul-skeletal Conventional	P	P					P	Note 2
Muscul-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric	P	P					P	Note 2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: ___ Transducer: X
Model: 65EC10EA
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal	P	P					P	Note 2
Trans-vaginal	P	P					P	Note 2
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 2

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: ___ Transducer: x
Model: 65EL052A
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P					P	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: —
Transducer: x
Model: 65EB105A
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N					N	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer N
Model: 6SEC10BD
510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Additional comments: Combined modes: B+M.
*Intraoperative includes abdominal, thoracic, and vascular.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Biopsy Guidance
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System: Transducer: *
Model: 7SL38EA
510(k) Number(s): K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

Transducer: —

System: —
Model: 75L53EA
510(k) Number(s): k113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic							P	Note 2
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P						
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac							P	Note 2
Peripheral Vascular	P	P						
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer x
Model: 75LT38EA
510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Muscullo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In vitro Diagnostic Device Evaluation and Safety

510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer x
Model: 7SLT9SBA
510(k) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance

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510K K113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer *
Model: 10L24BA
510(k) Number(s) k113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ=breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k113153

Diagnostic Ultrasound Indications for Use Form

System — Transducer x
Model: 10L2454
510(K) Number(s) K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric							N	Note 2
Small organ(specify)**	N	N						
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix B

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153